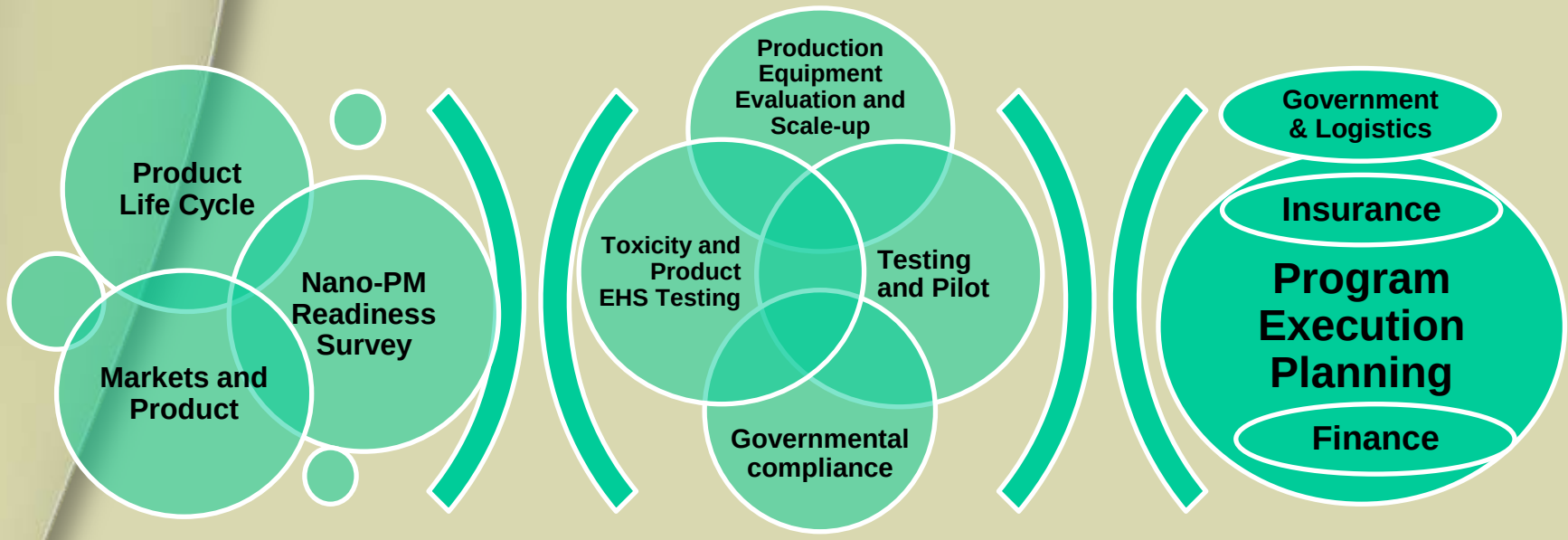
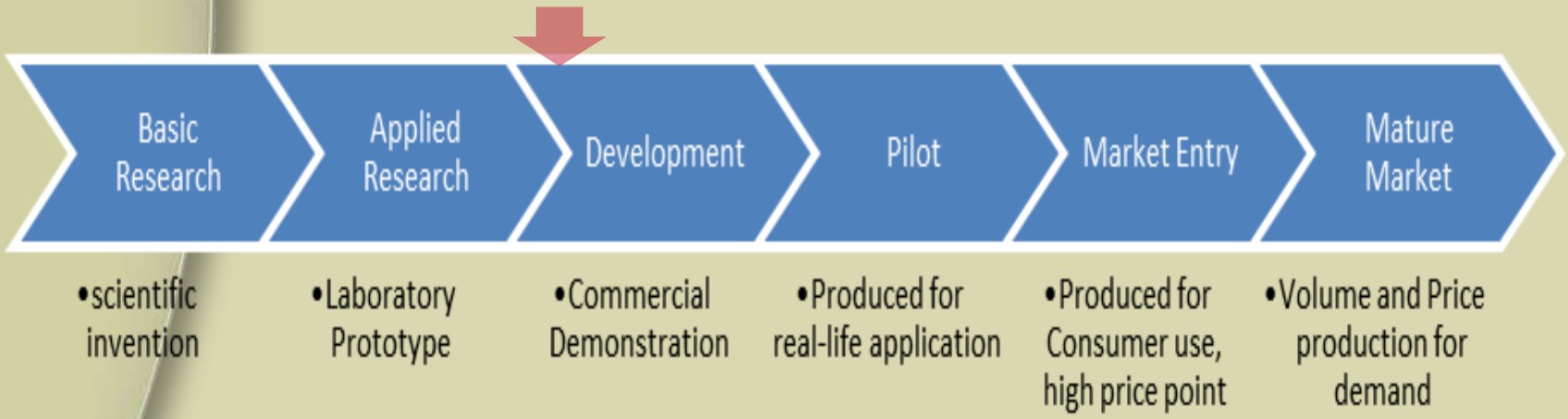
Converting One to a Million Scale-up Process for Nanotechnology Commercialization

Process Steps in Commercialization Planning



Understanding Product Life Cycle



Define position within the Product Life Cycle

- Each stage has Barrier Gate to the next level
- Each Gate exponentially transforms complexity from Technical issues to Commercial
- Time to Market is limited and may collapse
- Market Entry Gate is most volatile and where the "Valley of Death" is most prominent

Nanotechnology Scale-up to Commercialization "One to a Million"

Process Scale-up

Nanotechnology researchers skill set quickly becomes tested as complexity expands outside the product into business and facilities.

Manufacturing plant

Pilot Plant

Kilo Lab

Lab scale

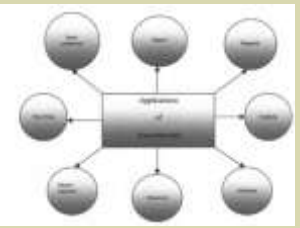
Cost

Complexity

Time

Nano-PM provides needed expertise in material science, process expansion, regulatory compliance, facility scoping, budgeting, and schedules.

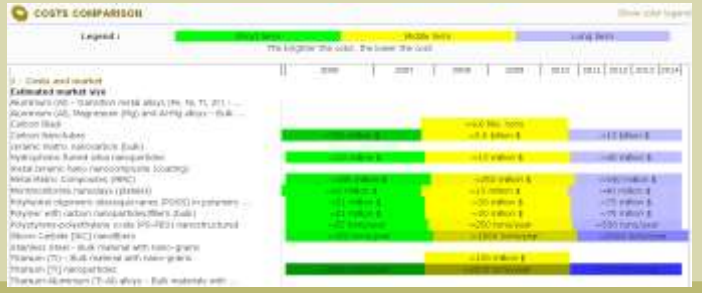
Understanding Markets and Products



- Applications of the Nanomaterial
- Identify End Products
- Define Customers
- Technical Competition, both nano and current technology.
- Size of current market, market growth and useful life (obsolescence)
- Unit Sale Price vs. Cost to Produce – current versus projected (estimated)

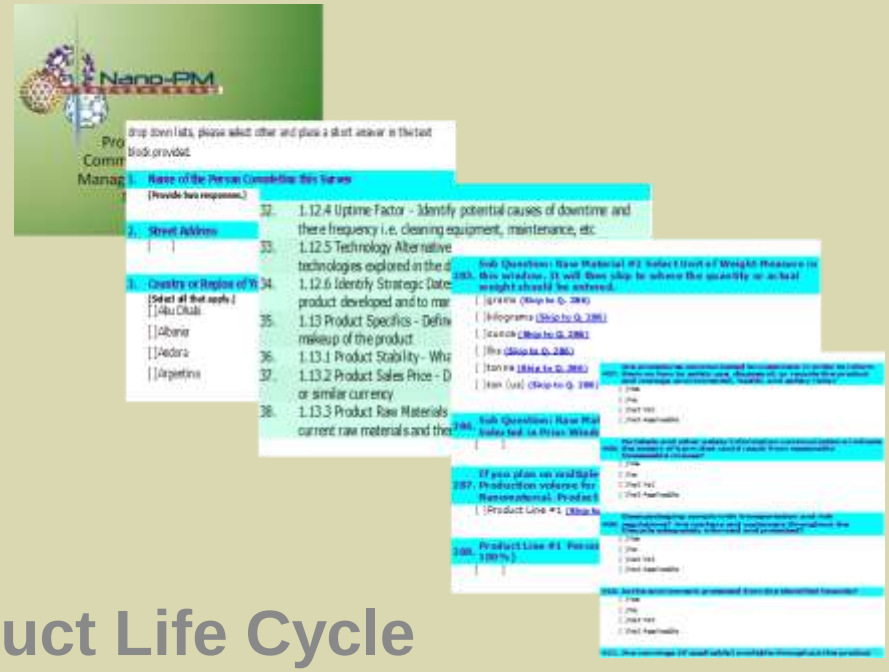
Market Potential

- Short term
- Medium term
- Long term



Understanding Readiness to Proceed

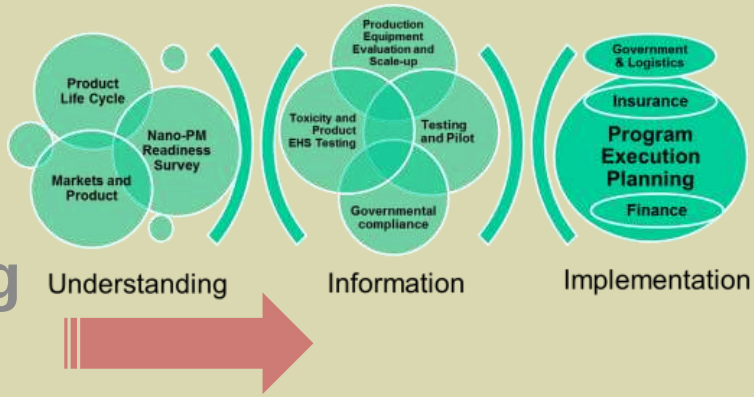
Nano-PM Readiness Survey



Understanding:

- **Position in Product Life Cycle**
- **Market and Product**
- **Readiness Scoring**

Allows transition to next step- Information Gathering



Information
Production Equipment - Lab to Plant

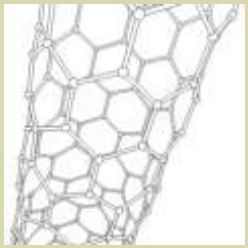
Identify Grams to Tons Requirement
The "One to a Million"

Scale-up of Equipment

- Full Equipment Set Defined
- Throughput and Reliability
- Costs and Options

Early Equipment Validation Trials

Information
Toxicity and EHS Testing



NanoTox

- Extensive product Testing
- Safety of Product during production
- Safety of Product for Use
- Long Term Impact on Health
- Impact on Environment

Nanotechnology Safety Services

nanoTox full array of services allows us to become your nanotechnology safety resource to support your nanotechnology commercialization efforts. Our services include R&D consulting, workplace safety, product safety, regulatory compliance, regulatory monitoring, toxicology testing and other similar support. Our scientists are highly skilled, and all our work meets GLP quality standards and is held in strict confidence.

nanoTox scientists have decades of experience working with nano and biological materials, including pharmacological and toxicological research using in vitro and in vivo pre-clinical models; preparation of the non-clinical portions of pharmaceutical and medical device submissions to regulatory agencies and the design and oversight of pre-clinical studies to meet research and business objectives. Our level of nanotoxicology expertise is unparalleled in the industry.

nanoTox industrial hygienists and medical management personnel also have decades of experience in professional R&D and industrial environments, our group of nationally recognized Toxicologists, Hygienists, and Occupational Physician's are experts in the subject of nanotechnology and stand prepared to bring your organization to the leading edge of compliance; quickly and without expensive evaluations or assessments.

Information
Governmental Compliance

Governmental Regulations

- Global Governmental Regulations
- International Standards for Nano
- Transportation Restrictions
- Evaluate ISO Standard 13121

Information
Testing and Pilot

Plan for Testing of Risks

Pilot Production

Pending Informational Issues found-

- **Run Equipment Pilots for Scale-up with Equipment Vendors**
- **Mitigation methods test for EHS issues**
- **Trial runs of products**
- **Pilot test of governmental approval**
- **Test batch transport and logistics issues**

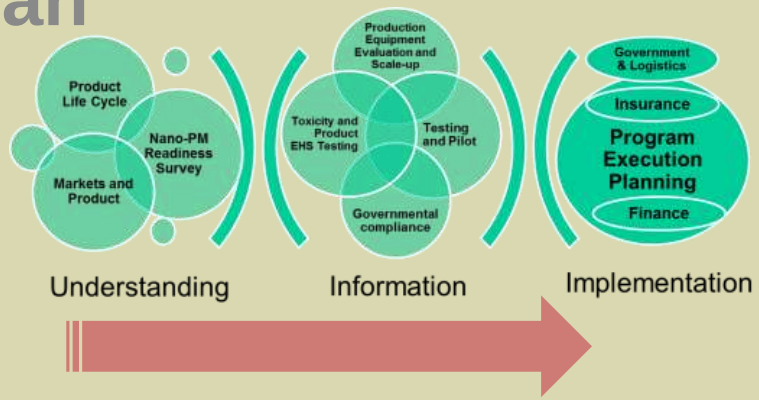
Information
Gathering Data for Informed Decisions

Information Gathering on:

- **Production Equipment**
- **Toxicity and EHS**
- **Governmental Regulations**
- **Testing and Pilots**

Allows transition to next step:

Implementation of a Clear Strategy and Program Execution Plan



Implementation
developing a Program Execution Plan

- Program Execution Plan
  - Executive Summary
  - Program Description
  - Technology
    - Product Positioning
    - Life of product and obsolescence
    - Usage and commercial viability
    - Geographic positioning of market
    - Geographic optimization of manufacturing
  - Phasing Plan and Schedules
  - Financing, Budgets and Costing
  - Organization and Resources
  - Risks
  - EHS
  - Quality
  - Administration and Governance
  - Operations

Implementation
Insurers & Risk Management

Alignment of Risk Stakeholders

- Information stage collected data focused on Insurer requirements
  - Questionnaire for Readiness focuses on key risk and insurance issues
  - Product manufacturing EHS risks – captured by NanoTox and toxicity testing
  - Long term Liabilities focused on end products
- Insurance Partners included in plan
- Risk Management

Program Execution Planning

- Captures all risk elements and how either insured or mitigated

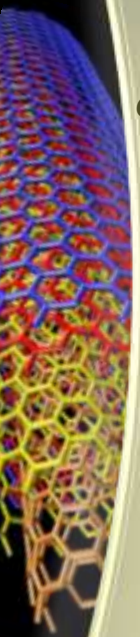
Implementation
Incorporating Investors

Alignment of Financial Stakeholders

- Information stage collected data focused on investor risk issues.
  - Questionnaire for Readiness defines areas of potential market revenue, costs, viability
  - Information stage develops equipment cost, detail capital needs, phasing of budgets
  - Business Model and projections
- Investment Partners included in plan
- Banks, Venture Capital, Funding

Program Execution Planning

- Captures financial model for budgets, cash flow, sources of funding, financial controls and governance



Implementation
Governments and Logistics

Alignment of External Stakeholders

- Information stage collected data focused on external positive or negative influences.
  - Questionnaire for Readiness outlines geographic areas, governmental and community support and or regulations
  - Information stage develops detail of regulatory environment and risks to product development
  - Information stage outlines community, supplier, or customer support or resistance
- Governmental issues and Logistics Providers included in plan

Program Execution Planning

- Captures influence in various sections of Risk, Financing, Schedule restraints, etc.

Checkpoint: Change and Flexibility in Planning

Technology and Innovation Fact:

Constant Change in Conditions-

Plans can be outdated immediately!

Establish:

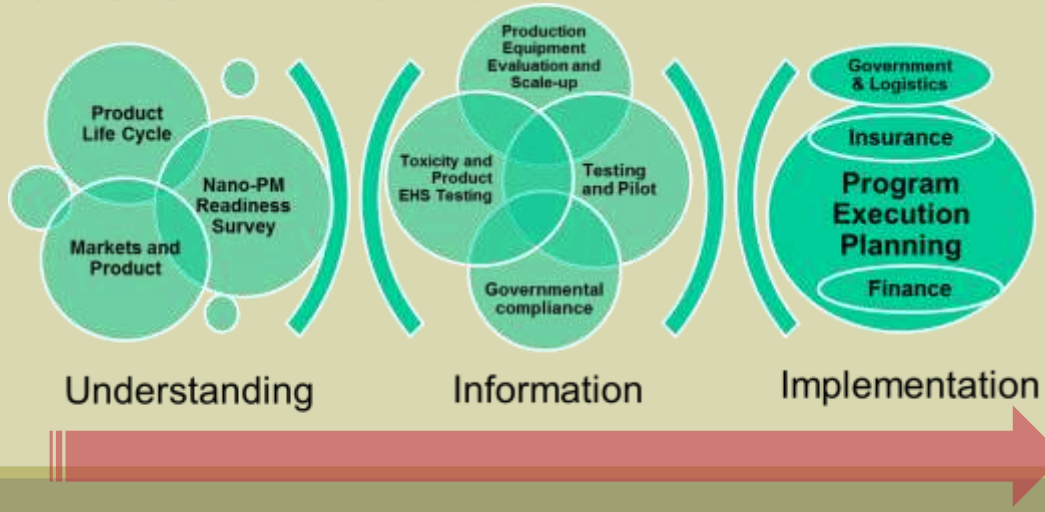
- Lessons Learned at each step
- Change Management
  - Know when you are changing
  - Know when to stop changing
  - Know when change is necessary

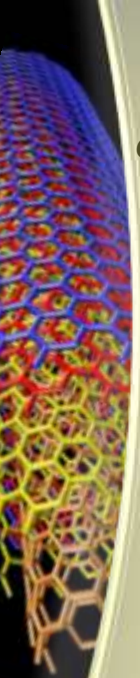
Questions
Process Steps for Commercialization

Following the Steps:

- Understanding
- Information Gathering
- Implementation Planning

- Allows small steps and clear investment of resources to get to the next level
- Reduces risks in each step
- Challenges Plans based on data
- Includes Stakeholders in Final Plan





Thank You!

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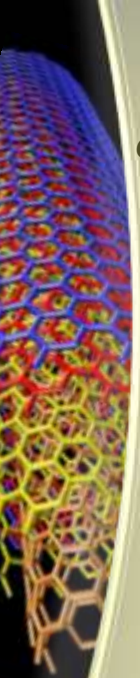


Backup Information

Nanotechnology Scale-up to Commercialization "One to a Million"

Preliminary Business Risk Matrix

Kickoff

- Submit Questionnaire
- Strategic dates
- Master project schedule Develop WBS
- Production startup schedule
- Team Coordination (Responsibility Matrix)
- Owner supplied info
- Location
- Black box equipment info
- Code studies/permits
- SHE status
- Product Validity
- Site visits
- Initial Funding

Technology Review

- Status of Lab Studies
- Rate Controlling Steps
- Life Safety Analysis
- Scale up Studies
- Product Stability
- Product Uniformity
- Raw Material Quality
- Process Modeling
- Turndown Ratio
- Nameplate Capacity
- Number of Trains
- Storage of Product
- Storage of Raw Materials
- Environmental
- Design Criteria

Facility & Ops Questionnaire

- Production Equipment Layout plot plans
- Major Manufacturing Equipment
- Design Criteria
- Life Safety Analysis
- Specialized HVAC Systems
- Building Architecture
- Special Piping /Plumbing
- Electrical
- Controls
- Security
- Environmental
- Materials of Construction

Estimate (s) Development

- Capital Cost Estimate
- Life Cycle
- Raw Materials
- Engineering
- Labor Study
- Priced Equipment List
- Materials Takeoff/ Pricing
- Site General Conditions
- Range Estimating
- Estimate Reviews
- Sales Price
- Capacity Requirements
- Net Present Worth
- Depreciation
- Internal Rate of Return
- Working Capital

Risk Matrix & Business Plan

- Value engineering (2)
- PSM support
- Debottlenecking Issues
- Hazard analysis
- SHE issues
- Constructability (2)
- Cost benefit analysis
- Time to Market
- Phasing Plans
- ROI Analysis

Our proposed initial step is to conduct a questionnaire matrix to determine the Technical and Business readiness to assist new Nano scale-up planning

Nanotechnology Scale-up to Commercialization "One to a Million"

Project Management Gate Process

1.0 Business Planning	2.0 Concept Facility Planning	3.0 Front End Design	4.0 Project Execution	5.0 Operation & Evaluation

MAJOR DELIVERABLES

1	2	3	4	5
▪ Business Need ▪ Project Sponsor ▪ Steering Team ▪ Project Charter ▪ Sales Forecast ▪ Sourcing Alternatives ▪ Target Site ▪ Technology Alternatives & Assessments ▪ Legal & Environmental ▪ Concept Designs Options ▪ Operate & Maintain ▪ Milestone Schedule ▪ ROM estimate (+/-50%) ▪ ROI Analysis	▪ Economic Evaluation of Alternatives ▪ Final Site Selection ▪ Conceptual Design Scope Including Flow Sheets ▪ Preliminary Project Execution Plan ▪ VAR–Value Added Record ▪ Risk Analysis ▪ Resource Commitments ▪ Readiness Review ▪ Master Schedule ▪ Conceptual Estimate (+/-30%)	▪ Project Design Basis ▪ Project Execution Plan ▪ Validation Master Plan ▪ Long Lead Equipment Order Placement ▪ Frozen Scope Document ▪ Facility Acceptance Criteria ▪ Risk Assessments ▪ Project Review ▪ Peer Review ▪ 3rd Party estimate Review ▪ Project Baseline Schedule ▪ CR Estimate (+/-10%)	▪ Environmental / Construction Permits ▪ Implement Project Controls to baselines ▪ Execution Contract Awards ▪ Completed Engineering Work Packages ▪ Completed Construction & Equipment Install ▪ Construction & Equipment ▪ Start-Up and Commissioning ▪ Owner Operations Move-In	▪ Stability Tests ▪ Performance ▪ Benchmark ▪ Certification or Accreditation ▪ Project Close-out ▪ Share Lessons Learned ▪ Identify Improvement Opportunities
Reject or Recycle / Decision Gate / Approve	Reject or Recycle / Decision Gate / Approve	Reject or Recycle / Decision Gate / Approve	Reject or Recycle / Decision Gate / Approve	Reject or Recycle / Decision Gate / Approve
Initial Capital Request ►	Supplemental request ►	Full Funding Request ►	Design / Build ►	Turn over to Operations

On completion of the Risk Matrix the focus will be to provide services for: Business(1.0) & Facility Plan (2.0) then Owner's Representation for (3.0-5.0)

Nanotechnology Scale-up to Commercialization "One to a Million"

Owners Rep Scope of Project Services

Front End 3.0

- Estimate
- Master project schedule
- Process flow diagrams
- Utility summary
- Utility flow diagrams
- Waste handling requirements
- Interlock classifications and descriptions
- Instrument list
- Piping requirements
- Special fittings list
- Building & site requirements
- Equipment arrangements and plot plans
- Power distribution plan
- Area electrical classification
- Process descriptions
- Detailed process control descriptions
- Process control hardware description
- Control system functional description

Design 4.0

- Feasibility studies
- Evaluation of alternatives
- Conceptual cost estimating
- Technology development
- Technology scale-up
- Process simplification
- Project economic analysis
- Site selection
- Environmental assessments
- PSM permitting–HAZOPS
- Dynamic simulation analysis
- Process engineering design
- Detailed engineering
- Equipment design
- Facilities design
- Instrumentation / Automation
- Systems integration
- CADD
- Reliability analysis
- Value engineering
- Constructability reviews
- Operability studies / manuals
- Environmental and permitting assistance

Procurement 4.0

- Global sourcing
- Shop evaluations
- Requisitioning/bid conditioning
- Contracts negotiations
- Vendor surveillance
- Logistics
- Expediting
- Quality assurance
- Vendor document control
- Warranty/service management
- Supply chain management

Construction 4.0

- Safety management
- Planning and scheduling
- Constructability
- Labor relations/hiring
- Community relations
- Craft training
- On-site materials management
- Site security
- Productivity management
- Quality assurance
- Field engineering
- Prefabricate/Modularize
- Mechanical integrity–PSM
- Construction support facilities
- Facility turnover/ commissioning

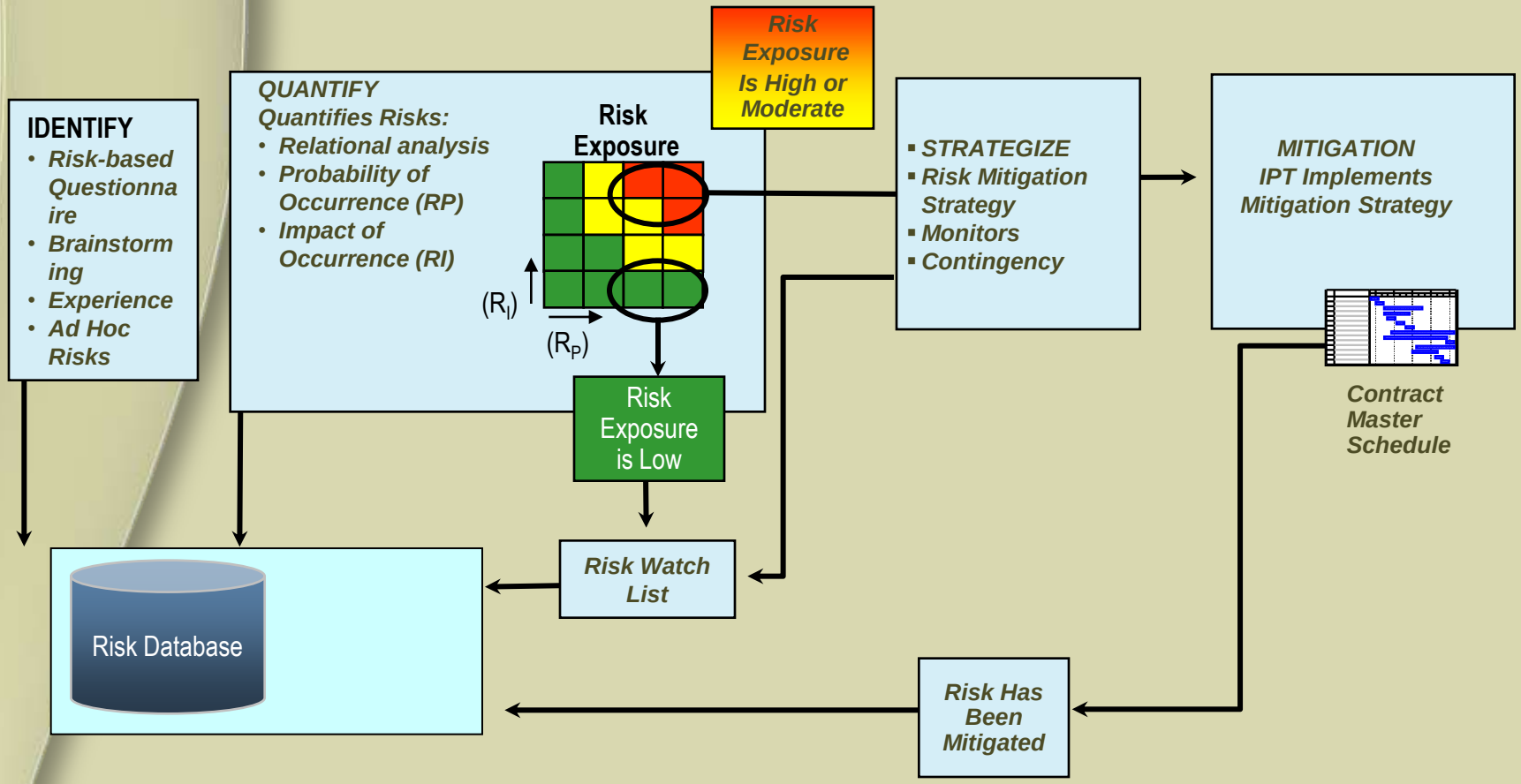
Operations & Maintenance 5.0

- Plant operations
- Maintenance/modifications
- Facilities management
- Operations training/start-up support
- Predicative maintenance
- PSM support
- Contract maintenance
- Warehouse management
- Facility management
- Debottlenecking
- Safety programs/management
- Asbestos/lead abatement
- Non destructive testing
- Shutdown/outage planning
- Environmental assessment
- Environmental permitting assistance
- Asset retirement

Project Oversight is needed in the downstream execution steps as the Nanomaterial supplier & Nanomaterial purchaser move forward

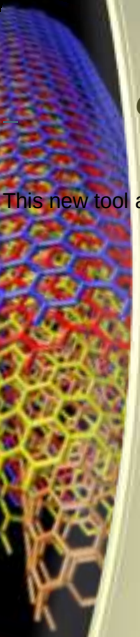
Nanotechnology Scale-up to Commercialization "One to a Million"

Risk Management Highlights Challenges



Our Risk Management Process to Identify, Quantify, Strategize and Minimize Risks, starts early and is continuous along the entire project lifecycle

Nanotechnology Scale-up to Commercialization "One to a Million"



Nanotechnology Scale-up to Commercialization "One to a Million"

This new tool allows you to search the U.S. state by state to locate nanotechnology-related facilities,